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There are no current objections or hearings present

## Renewal Interest

COMPUTER PACKAGES INC 414 Hungerford Drive, Suite 300, Rockville, M. D. 20850, United States of America

## Applicant / Patentee & Licensee History

No applicants nor licensees on record or public access is restricted

## Inventors

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## Your Selection Criteria

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NEW ZEALAND

PATENTS ACT 1953

# COMPLETE SPECIFICATION

Title of Invention:

Method and apparatus for direct laser cutting of metal stents

Name, address and nationality of
applicant(s) as in international
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280547

NEW ZEALAND

PATENTS ACT, 1953



No:

Date:

# COMPLETE SPECIFICATION

## METHOD AND APPARATUS FOR DIRECT LASER CUTTING OF METAL STENTS

We, ADVANCED CARDIOVASCULAR SYSTEMS, INC., a corporation organised and existing under the laws of the State of California, United States of America, having a place of business at 3200 Lakeside Drive, Santa Clara, California 95052, United States of America, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:



(followed by page -1a-)

## BACKGROUND OF THE INVENTION

This invention relates generally to improvements in the manufacture of expandable metal stents and, more particularly, to new and improved methods and apparatus for direct laser cutting of metal stents and providing stents of enhanced structural quality.

Stents are expandable endoprosthesis devices which are adapted to be implanted into a body lumen of a patient, such as a blood vessel, to maintain the patency of the vessel. These devices typically are used in the treatment of atherosclerotic stenosis in blood vessels and the like.

In the medical arts, stents generally are tubular-shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. Stents particularly are suitable for use to support and hold back a dissected arterial lining which can occlude the fluid passageway.

Various means have been provided to deliver and implant stents. One method frequently described for delivering a stent to a desired intraluminal location includes mounting the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the body lumen of a patient, inflating the balloon on the catheter to expand the stent into a permanently expanded condition and then deflating the balloon and removing the catheter.

One example of a particularly useful expandable stent is a stent which is relatively flexible along its longitudinal axis to facilitate delivery through tortuous body lumens, but which is stiff and stable enough radially when in an expanded condition so as to maintain the patency of a body lumen such as

an artery when implanted within the lumen. Such a desirable stent typically includes a plurality of radially expandable cylindrical elements which are relatively independent in their ability to expand and to flex relative to one another. The individual radially expandable cylindrical elements of the stent are precisely dimensioned so as to be longitudinally shorter than their own diameters. Interconnecting elements or struts extending between adjacent cylindrical elements provide increased stability and a preferable position to prevent warping of the stent when it is expanded. The resulting stent structure is a series of radially expandable cylindrical elements which are spaced closely enough longitudinally so that small dissections in the wall of a body lumen may be pressed back into position against the lumenal wall, but not so closely as to compromise the longitudinal flexibility of the stent. The individual cylindrical elements may rotate slightly relative to adjacent cylindrical elements without significant deformation, cumulatively resulting in a stent which is flexible along its length and about its longitudinal axis, but which is still very stiff in the radial direction in order to resist collapse.

The aforedescribed stents generally have a precisely laid out circumferential undulating pattern, e.g., serpentine. The transverse cross-section of the undulating component of the cylindrical element is relatively small and preferably has an aspect ratio of about two to one (2:1) or about one-half to one (0.5/1). A one to one (1:1) aspect ratio has been found to be particularly suitable. The open reticulated structure of the stent allows for the perfusion of blood over a large portion of the arterial wall, which can improve the healing and repair of a damaged arterial lining.

The radial expansion of the expandable cylinder deforms the undulating pattern similar to changes in a waveform which result from decreasing the amplitude and the frequency. Preferably, the undulating patterns of the individual

cylindrical structures are in phase with each other in order to prevent the contraction of the stent along its length when it is expanded. The cylindrical structures of the stent are plastically deformed when expanded so that the stent will remain in the expanded condition and, therefore, the structures must be sufficiently rigid when expanded to prevent collapse during deployment of the stent. Upon expansion of the stent, portions of the undulating pattern will tip outwardly resulting in projecting members on the outer surface of the expanded stent. These projecting members tip radially outwardly from the outer surface of the stent and embed into the vessel wall and help secure the expanded stent so that it does not move once it is implanted.

The elongated elements which interconnect adjacent cylindrical elements should have a precisely defined transverse cross-section similar to the transverse dimensions of the undulating components of the expandable cylindrical elements. The interconnecting elements may be formed as a unitary structure with the expandable cylindrical elements from the same intermediate product, such as a tubular element, or they may be formed independently and connected by suitable means, such as by welding or by mechanically securing the ends of the interconnecting elements to the ends of the expandable cylindrical elements. Preferably, all of the interconnecting elements of a stent are joined at either the peaks or the valleys of the undulating structure of the cylindrical elements which form the stent. In this manner, there is no shortening of the stent upon expansion.

The number and location of elements interconnecting adjacent cylindrical elements can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded, as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen

(followed by page 4a)

which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stent, the more easily and the more safely it can be delivered to the implantation site.

It will be apparent from the foregoing that conventional stents are very high-precision, relatively fragile devices and, ideally, the most desirable metal stents incorporate a fine precision structure cut from a very small diameter, thin-walled cylindrical tube. In this regard, it is extremely important to make precisely-dimensioned, smooth, narrow cuts in the stainless tubes in extremely fine geometries without damaging the narrow struts that make up the stent structure. While the various cutting processes, including chemical etching, heretofore have been used to form such expandable metal stents and have been adequate, improvements have been sought to provide stents of enhanced structural quality in terms of resolution, reliability and yield.

Accordingly, those concerned with the development, manufacture and use of metal stents long have recognized the need for the improved manufacturing processes for such stents. The present invention fulfills these needs.

## SUMMARY OF THE INVENTION

Briefly, and in general terms, the present specification discloses a new and improved method and apparatus for direct laser cutting of metal stents enabling greater precision, reliability, structural integrity and overall quality, without burrs, slag or other imperfections that otherwise might hamper stent integrity and performance. The present specification also discloses and claims a longitudinal flexible stent.

In particular, the present invention as claimed broadly consists in a longitudinal flexible stent for implanting

in a body lumen, comprising: a plurality of cut cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis, each cylindrical element having a rectangular cross-section from one cut edge to another; and a plurality of connecting elements for interconnecting said cut cylindrical elements, said connecting elements configured to interconnect said cylindrical elements that are adjacent to each other.

Basically, the present specification discloses an improved system for producing metal stents with a fine precision structure, cut from a small diameter, thin-walled, cylindrical tube. The tubes typically are made of stainless steel and are

fixtured under a laser and positioned utilizing a computer numerical control (CNC) fixture to generate a very intricate and precise pattern. Due to the thin-wall and the small geometry of the stent pattern, it is necessary to have very precise control of the laser, its power level, the focus spot size, and the positioning of the laser cutting path.

In a presently preferred embodiment of the manufacture of the stent, in order to minimize the heat input, to avoid thermal distortion, uncontrolled burn out of the metal, and metallurgical damage due to excessive heat, a Q-switched Nd:YAG(neodymium: yttrium aluminum garnet) laser that is frequency doubled to produce a green beam at 532 nanometers is used Q-switching produces very short pulses (< 100 nanoseconds) of high peak powers (kilowatts), low energy per pulse (≤3 millijoules), at high pulse rates (up to 40 kilohertz). The frequency doubling of the beam from 1.06 microns to 0.532 microns allows the beam to be focused to a spot size that is 2 times smaller than is a non-frequency doubled beam and, therefore, the power density is increased by a factor of four. With all of these parameters, it is possible to make smooth, narrow cuts in the stainless tubes in very fine geometries without damaging the narrow struts that comprise the stent structure.

In addition to the laser and the CNC positioning equipment, the optical delivery system used in the manufacture of the stent preferably includes a beam expander to increase the laser beam diameter; a circular polarizer to eliminate polarization effects in metal cutting; provisions for a spatial filter; a binocular viewing head and focusing lens; and a coaxial gas jet that provides for the introduction of a gas stream that surrounds the focused beam and is directed along the beam axis. The coaxial gas jet nozzle is centered around the focused beam with approximately 0.25 millimeters (0.01 inch) between the tip of the nozzle and the tubing. The jet is pressurized with oxygen at 3.87 cm-Hg (20 lbs/in$^2$) and is

directed at the tube with the focused laser beam exiting the tip of the nozzle. The oxygen reacts with the metal to assist in the cutting process very similar to what occurs with oxyacetylene cutting. The focused laser beam acts as an ignition source and controls the reaction of the oxygen with the metal. In this manner, it is possible to cut the material with a very fine kerf with precision. In order to prevent burning by the beam and/or molten slag on the far wall of the tube inside diameter, a mandrel, preferably made of stainless steel, is placed inside the tube and is allowed to roll on the bottom of the tube as the pattern is cut. This mandrel acts as a beam/debris block, protecting the far wall inside diameter. The use of a protective mandrel in a method of making an expandable metal stent using a laser beam is the subject of the invention claimed in New Zealand Patent Specification No. 331033 divided out of the present specification.

The cutting process utilizing oxygen with the finely focused green beam results in a very narrow kerf (approximately 0.013 millimeters (0.0005 inch) with the molten slag re-solidifying along the cut. This traps the cut-out scrap of the pattern and which requires further processing to remove. In order to remove the slag debris from the cut allowing the scrap to be removed from the remaining stent pattern, it is desirable to soak the cut tube in a solution of hydrochloric acid (HCL) for a selected time and temperature. Before it is soaked, the tube is placed in a bath of alcohol and water solution and ultrasonically cleaned for approximately 1 minute to remove the loose debris left from the cutting operation. After soaking, the tube then is ultrasonically cleaned in the heated HCL for a period of time dependent upon the wall thickness. To prevent cracking or breaking of the struts attached to the material left at the two ends of the stent pattern as a result of harmonic oscillations induced by the ultrasonic cleaner, a mandrel is placed down the center of the tube during the cleaning and scrap removal process. At completion of this process, the stent structures are rinsed in water. They are then ready for electropolishing.

Hence, the new and improved method and apparatus for direct laser cutting of metal stents

makes accurate, reliable, high resolution, expandable stents with patterns having smooth, narrow cuts and very fine geometries, including longitudinal flexible stents as claimed in the present specification.

The above and other objects and advantages of this invention will be apparent from the following more detailed description when taken in conjunction with the accompanying drawings of exemplary embodiments.

## DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an elevational view, partially in section, of a stent embodying features of the invention which is mounted on a delivery catheter and disposed within a damaged artery;

FIG. 2 is an elevational view, partially in section, similar to that shown in FIG. 1 wherein the stent is expanded within a damaged artery, pressing the damaged lining against the arterial wall;

FIG. 3 is an elevational view, partially in section showing the expanded stent within the artery after withdrawal of the delivery catheter;

FIG. 4 is a perspective view of a stent features of the invention in an unexpanded state, with one end of the stent being shown in an exploded view to illustrate the details thereof;

FIG. 5 is a plan view of a flattened section of a stent of the invention which illustrates the undulating pattern of the stent shown in FIG. 4;

FIG. 5a is a sectional view taken along the line 5a-5a in FIG. 5;

FIG. 6 is a schematic representation of equipment for selectively cutting the tubing in the manufacture of stents, in accordance with the present invention;

FIG. 7 is an elevational view of a system for cutting an appropriate pattern by laser in a metal tube to form a stent, in accordance with the invention;

FIG. 8 is a plan view of the laser head and optical delivery subsystem for the laser cutting system shown in FIG. 7;

FIG. 9 is an elevational view of a coaxial gas jet, rotary collet, tube support and beam blocking apparatus for use in the system of FIG. 7;

FIG. 10 is a sectional view taken along the line 10-10 in FIG. 9;

FIG. 11 is an elevational and schematic drawing of laser beam diameter versus spot size and depth of focus; and

FIG. 12 is an elevational and schematic drawing of focal length versus spot size and depth of focus.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, and particularly to FIG. 1 thereof, there is shown a stent 10 which is mounted onto a delivery catheter 11. The stent 10 is a high-precision patterned tubular device. The stent 10 typically comprises a plurality of radially expanded cylindrical elements 12 disposed generally coaxially and interconnected by elements 13 disposed between adjacent cylindrical elements. The delivery catheter 11 has an expandable portion or balloon 14 for expanding of the stent 10 within an artery 15. The artery 15, as shown in FIG.

1 has a dissected lining 16 which has occluded a portion of the arterial passageway.

The typical delivery catheter 11 onto which the stent 10 is mounted, is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and ionomers such as that manufactured under the tradename "SURLYN" by the Polymer Products Division of the E. I. Du Pont deNemours Company. Other polymers also may be used. In order for the stent 10 to remain in place on the balloon 14 during delivery to the site of the damage within the artery 15, the stent 10 is compressed onto the balloon. A retractable protective delivery sleeve 20, as described in European Patent Application No. 0540290, may be provided to further

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insure that the stent stays in place on the expandable portion of the delivery catheter 11 and to prevent abrasion of the body lumen by the open surface of the stent 20 during delivery to the desired arterial location. Other means for securing the stent 10 onto the balloon 14 also may be used, such as providing collars or ridges on the ends of the working portion, i.e., the cylindrical portion, of the balloon.

Each radially expandable cylindrical element 12 of the stent 10 may be independently expanded. Therefore, the balloon 14 may be provided with an inflated shape other than cylindrical, e.g., tapered, to facilitate implantation of the stent 10 in a variety of body lumen shapes.

The delivery of the stent 10 is accomplished in the following manner. The stent 10 is first mounted onto the inflatable balloon 14 on the distal extremity of the delivery catheter 11. The balloon 14 is slightly inflated to secure the stent 10 onto the exterior of the balloon. The catheter-stent assembly is introduced to the vasculature of the patient in a

conventional Seldinger technique through a guiding catheter (not shown). A guidewire 18 is disposed across the damaged arterial section having the detached or dissected lining 16 and then the catheter-stent assembly is advanced over a guidewire 18 within the artery 15 until the stent 10 is directly under the detached lining 16. The balloon 14 of the catheter is expanded, expanding the stent 10 against the artery 15, which is illustrated in FIG. 2. While not shown in the drawing, the artery 15 is preferably expanded slightly by the expansion of the stent 10 to seat or otherwise fix the stent 10 to prevent movement. In some circumstances during the treatment of stenotic portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid therethrough.

The stent 10 serves to hold open the artery 15 after the catheter 11 is withdrawn, as illustrated by FIG. 3. Due to the formation of the stent 10 from an elongated tubular member, the undulating component of the cylindrical elements of the stent 10 is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical elements are pressed into the wall of the artery 15 and as a result do not interfere with the blood flow through the artery 15. The cylindrical elements 12 of the stent 10 which are pressed into the wall of the artery 15 eventually will be covered with endothelial cell growth which further minimizes blood flow interference. The undulating portion of the cylindrical sections 12 provide good tacking characteristics to prevent stent movement within the artery. Further, the closely spaced cylindrical elements 12 at regular intervals provide uniform support for the wall of the artery 15, and consequently are well adapted to tack up and hold in place small flaps or dissections in the wall of the artery 15, as illustrated in FIGS. 2 and 3.

FIG. 4 is an enlarged perspective view of the stent 10 shown in FIG. 1 with one end of the stent shown in an

exploded view to illustrate in greater detail the placement of interconnecting elements 13 between adjacent radially-expandable cylindrical elements 12. Each pair of the interconnecting elements 13 on one side of a cylindrical element 12 preferably are placed to achieve maximum flexibility for a stent. In the embodiment shown in FIG. 4, the stent 10 has three interconnecting elements 13 between adjacent radially expandable cylindrical elements 12 which are 120° apart. Each pair of interconnecting elements 13 on one side of a cylindrical element 12 are offset radially 60° from the pair on the other side of the cylindrical element. The alternation of the interconnecting elements results in a stent which is longitudinally flexible in essentially all directions. Various configurations for the placement of interconnecting elements are possible. However, as previously mentioned, all of the interconnecting elements of an individual stent should be secured to either the peaks or valleys of the undulating structural elements in order to prevent shortening of the stent during the expansion.

The number of undulations may also be varied to accommodate placement of interconnecting elements 13, e.g., at the peaks of the undulations or along the sides of the undulations as shown in FIG. 5.

As best observed in FIGS. 4 and 5, cylindrical elements 12 are in the form of a serpentine pattern. As previously mentioned, each cylindrical element 12 is connected by interconnecting elements 13. The serpentine pattern is made up of a plurality of U-shaped members, W-shaped members, and Y-shaped members, each having a different radius so that expansion forces are more evenly distributed over the various members.

The afordescribed illustrative stent 10 and similar stent structures can be made in many ways. However, the preferred method of making the stent is to cut a thin-walled

tubular member, such as stainless steel tubing, to remove portions of the tubing in the desired pattern for the stent, leaving relatively untouched the portions of the metallic tubing which are to form the stent. In accordance with the invention, it is preferred to cut the tubing in the desired pattern by means of a machine-controlled laser as illustrated schematically in FIG. 6.

The tubing may be made of suitable biocompatible material such as stainless steel. The stainless steel tube may be Alloy type: 316L SS, Special Chemistry per ASTM F138-92 or ASTM F139-92 grade 2; Special Chemistry of type 316L per ASTM F138-92 or ASTM F139-92 Stainless Steel for Surgical Implants in weight percent.

| | |
|---|---|
| Carbon (C) | 0.03% max. |
| Manganese (Mn) | 2.00% max. |
| Phosphorous (P) | 0.025% max. |
| Sulphur (S) | 0.010% max. |
| Silicon (Si) | 0.75% max. |
| Chromium (Cr) | 17.00 - 19.00% |
| Nickel (Ni) | 13.00 - 15.50% |
| Molybdenum (Mo) | 2.00 - 3.00% |
| Nitrogen (N) | 0.10% max. |
| Copper (Cu) | 0.50% max. |
| Iron (Fe) | Balance |

The stent diameter is very small, so the tubing from which it is made necessarily must also have a small diameter. Typically the stent has an outer diameter on the order of about 1.52 millimeters (0.06 inch) in the unexpanded condition, the same outer diameter of the tubing from which it is made, and can be expanded to an outer diameter of 2.54 millimeters (0.1 inch) or more. The wall thickness of the tubing is about 0.076 millimeters (0.003 inch).

Referring to FIG. 6, the tubing 21 is put in a fixture having rotatable collets 22 of a machine-controlled apparatus 23 for positioning the tubing 21 relative to a laser 24. According to machine-encoded instructions, the tubing 21 is rotated and moved longitudinally relative to the laser 24 which also is machine-controlled. The laser selectively

removes the material from the tubing by ablation and a pattern is cut into the tube. The tube therefore is cut into the discrete pattern of the finished stent.

The process of cutting a pattern for the stent into the tubing is automated except for the loading and unloading of the length of tubing. Referring again to FIG. 6 loading may be accomplished for example, using a CNC-opposing collet fixture 22 for axial rotation of the length of tubing, in conjunction with a CNC X/Y table 25 to move the length of tubing axially relatively to a machine-controlled laser as described. The entire space between collets can be patterned using the $CO_2$ laser set-up of the foregoing example. The program for control of the apparatus is dependent on the particular configuration used and the pattern to be ablated in the coating.

Referring now to FIGS. 7-10 of the drawings, there is shown a process and apparatus, in accordance with the invention, for producing metal stents with a fine precision structure cut from a small diameter thin-walled cylindrical tube. Cutting a fine structure (0.09 millimeter (0.0035 inch) web width) requires minimal heat input and the ability to manipulate the tube with precision. It also is necessary to support the tube yet not allow the stent structure to distort during the cutting operation. In order to successfully achieve the desired end results, the entire system must be configured very carefully. The tubes are made of stainless steel with an outside diameter of 1.524 millimeters to 1.676 millimeters (0.060 inch to 0.066 inch) and a wall thickness of 0.051 millimeters to 0.102 millimeters (0.002 inch to 0.004 inch). These tubes are fixtured under a laser and positioned using a CNC to generate a very intricate and precise pattern. Due to the thin wall and the small geometry of the stent pattern (0.09 millimeter (0.0035 inch) typical web width), it is necessary to have very precise control of the laser, its power level, the focused spot size, and the precise positioning of the laser cutting path.

In order to minimize the heat input into the stent structure, which prevents thermal distortion, uncontrolled burn out of the metal, and metallurgical damage due to excessive heat, and thereby produce a smooth debris-free cut, a Q-switched Nd:YAG laser typically available from Quantronix of Hauppauge, New York is used, that is frequency doubled to produce a green beam at 532 nanometers. Q-switching produces very short pulses (<100 nanoseconds) of high peak powers (kilowatts), low energy per pulse (≤3 millijoules), at high pulse rates (up to 40 kilohertz). The frequency doubling of the beam from 1.06 microns to 0.532 microns allows the beam to be focused to a spot size that is 2 times smaller than a non-frequency doubled beam, therefore increasing the power density by a factor of 4 times. With all of these parameters, it is possible to make smooth, narrow cuts in the stainless tubes in very fine geometries without damaging the narrow struts that make up the stent structure. Hence, the system of the present invention makes it possible to adjust the laser parameters to cut narrow kerf width which will minimize the heat input into the material.

The positioning of the tubular structure requires the use of precision CNC equipment such as that manufactured and sold by the Anorad Corporation. In addition, a unique rotary mechanism has been provided that allows the computer program to be written as if the pattern were being cut from a flat sheet. This allows both circular and linear interpolation to be used in the programming. Because the finished structure of the stent is very small, a precision drive mechanism is required that supports and drives both ends of the tubular structure as it is cut. Since both ends are driven, they must be aligned and precisely synchronized, otherwise the stent structure would twist and distort as it is being cut. A suitable computer program for controlling the CNC equipment is enclosed herewith as Appendix A.

The optical system which expands the original laser beam, delivers the beam through a viewing head and focuses the beam onto the surface of the tube, incorporates a coaxial gas jet and nozzle that helps to remove debris from the kerf and cools the region where the beam interacts with the material as the beam cuts and vaporizes the metal. It also is necessary to block the beam as it cuts through the top surface of the tube and to prevent the beam, along with the molten metal and debris from the cut, from impinging on the opposite surface of the tube.

In addition to the laser and the CNC positioning equipment, the optical delivery system includes a beam expander to increase the laser beam diameter, a circular polarizer, typically in the form of a quarter wave plate, to eliminate polarization effects in metal cutting, provisions for a spatial filter, a binocular viewing head and focusing lens, and a coaxial gas jet that provides for the introduction of a gas stream that surrounds the focused beam and is directed along the beam axis. The coaxial gas jet nozzle (0.457 millimeter (0.018 inch) inner diameter (I.D.)) is centered around the focused beam with approximately 0.254 millimeter (0.010 inch) between the tip of the nozzle and the tubing. The jet is pressurized with oxygen at 3.87 cm-Hg (20 lbs/in$^2$) and is directed at the tube with the focused laser beam exiting the tip of the nozzle (0.457 millimeter (0.018 inch) diameter). The oxygen reacts with the metal to assist in the cutting process very similar to the reaction that takes place during oxyacetylene cutting. The focused laser beam acts as an ignition source and controls the reaction of the oxygen with the metal. In this manner, it is possible to cut the material with a very fine kerf with precision. In order to prevent burning by the beam and/or molten slag on the far wall of the tube inner diameter (I.D.) a stainless steel mandrel (approximately 0.864 millimeter (0.034 inch) diameter) is placed inside the tube and is allowed to roll on the bottom of

the tube as the pattern is cut. This acts as a beam/debris block protecting the far wall I.D.

Alternatively, this debris collection can accomplished by inserting a second tube, inside the stent tube which has an opening to trap the excess energy in the beam that is transmitted through the kerf as well as the debris that is ejected from the laser-cut kerf. A vacuum or positive pressure can be placed in this shielding tube to remove the collected of debris.

Another technique that could be used to remove the debris from the kerf and to cool the surrounding material would be to use the inner beam blocking tube as an internal gas jet. By sealing one end of the tube, making a small hole in the side, and placing it directly under the focused laser beam, gas pressure could be applied creating a small jet that would force the debris out of the laser-cut kerf from the inside out. This would eliminate any debris from forming or collecting on the inside of the stent structure. It would place all the debris on the outside. With the use of special protective coatings, the resultant debris then easily could be removed.

In most cases, the gas utilized in the jets may be reactive or non-reactive (inert). In the case of reactive gas, oxygen or compressed air is used. Compressed air is used in this application because it offers more control of the material removed and reduces the thermal effects of the material itself. Inert gas such as argon, helium, or nitrogen can be used to eliminate any oxidation of the cut material. The result is a cut edge with no oxidation, but there usually is a tail of molten material that collects along the exit side of the gas jet which must be removed mechanically or chemically after the cutting operation.

The cutting process utilizing oxygen with the finely focused green beam results in a very narrow kerf (approximately

0.0127 millimeter (0.0005 inch)) with the molten slag re-solidifying along the cut. This traps the cut-out scrap of the pattern which requires further processing to remove. In order to remove the slag debris from the cut allowing the scrap to be removed from the remaining stent pattern, it is necessary to soak the cut tube in a solution of HCL for approximately 8 minutes at a temperature of approximately 55° C. Before it is soaked, the tube is placed in a bath of alcohol and water solution and ultrasonically is cleaned for approximately 1 minute, to remove the loose debris left from the cutting operation. After soaking, the tube then is ultrasonically cleaned in the heated HCL for 1 to 4 minutes, depending upon the wall thickness. To prevent cracking or breaking of the struts attached to the material left at the two ends of the stent pattern, as a result of harmonic oscillations induced by the ultrasonic cleaner, a mandrel is placed down the center of the tube during the cleaning and scrap removal process. At completion of this process, the stent structures are rinsed in water. They are now ready for electropolishing.

The stents preferably are electrochemically polished, in an acidic aqueous solution such as a solution marketed under the tradename ELECTRO-GLO #300 by the ELECTRO-GLO Co., Inc. in Chicago, Illinois, which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 43.3 to 57.2°C (110 to 135°F) and the current density is about 0.4 to about 1.5 amps/in.$^2$. Cathode to anode area should be at least about two to one. The stents further may be treated if desired, for example by applying a biocompatible coating.

Referring now more particularly to FIGS. 11 and 12, it will be apparent that both focused laser spot size and depth of focus can be controlled by selecting beam diameter (FIG. 11) and focal length for the focusing lens (FIG. 12). It will be apparent from FIGS. 11 and 12 that increasing laser beam

diameter, or reducing lens focal length, reduces spot size at the expense of depth of field.

Direct laser cutting produces edges which are essentially perpendicular to the axis of the laser cutting beam, in contrast with chemical etching and similar processes which produce pattern edges that are angled. Hence, the laser cutting process of the present invention essentially provides stent cross-sections, from cut-to-cut, which are square or rectangular rather than trapezoidal; see FIG. 5a. The resulting stent structure provides superior performance.

It will be apparent from the foregoing that the present invention provides a new and improved method and apparatus for direct laser cutting of metal stents enabling greater precision, reliability, structural integrity and overall quality, without burrs, slag or other imperfections which might otherwise hamper stent integrity and performance. While the invention has been illustrated and described herein in terms of its use as an intravascular stent, it will be apparent to those skilled in the art that the stent can be used in other instances such as to expand prostatic urethras in cases of prostate hyperplasia. Other modifications and improvements may be made without departing from the scope of the invention.

It will be apparent from the foregoing that, while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT WE CLAIM IS:

1. A longitudinal flexible stent for implanting in a body lumen, comprising:

a plurality of cut cylindrical elements which are independently expandable in the radial direction and which are interconnected so as to be generally aligned on a common longitudinal axis, each cylindrical element having a rectangular cross-section from one cut edge to another; and

a plurality of connecting elements for interconnecting said cut cylindrical elements, said connecting elements configured to interconnect said cylindrical elements that are adjacent to each other.

2. The stent of claim 1, wherein said plurality of cut cylindrical elements include a plurality of peaks and valleys having a serpentine pattern.

3. The stent of claim 2, wherein said plurality of peaks and valleys include a plurality of U-shaped members, a plurality of Y-shaped members, and a plurality of W-shaped members, some of said U-shaped, Y-shaped, and W-shaped members being interconnected.

4. The stent of claim 1, wherein at least some of said plurality of cut cylindrical elements tip radially outwardly to form outwardly projecting edges upon radial expansion of said stent.

5. The stent of claim 1, wherein said cut cylindrical elements are capable of retaining their expanded condition upon the expansion thereof.

6. The stent of claim 1, wherein said stent is formed of stainless steel.

7. The stent of claim 1, wherein said stent is formed from a single piece of tubing.

8. A longitudinal flexible stent for implanting in a body lumen substantially as herein described with reference to the accompanying drawings.

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FIG. 1

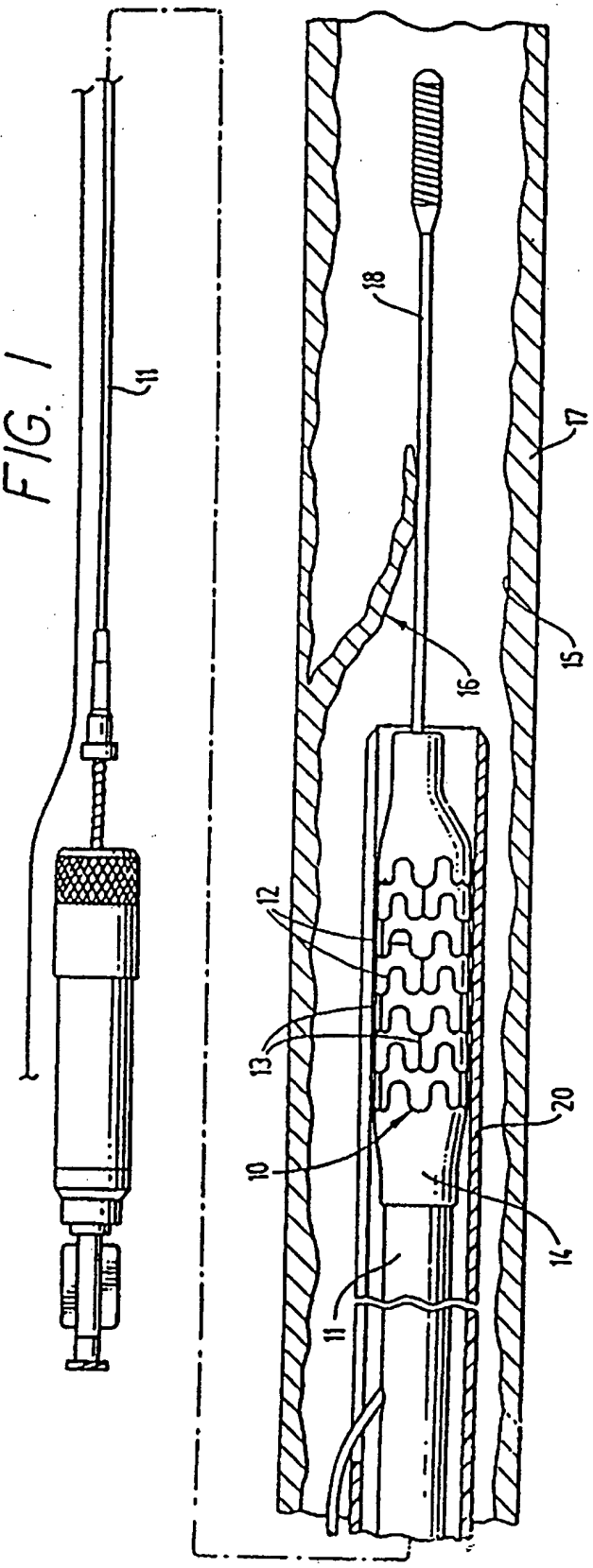


FIG. 3

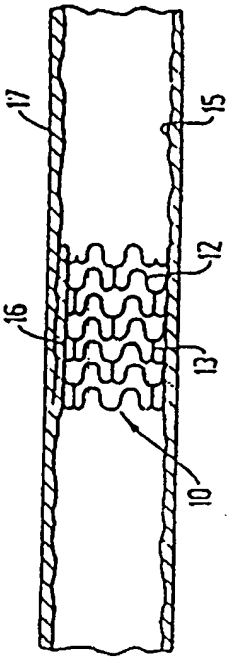


FIG. 2

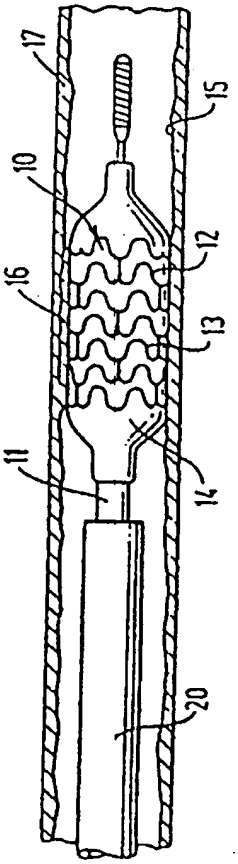


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FIG. 4

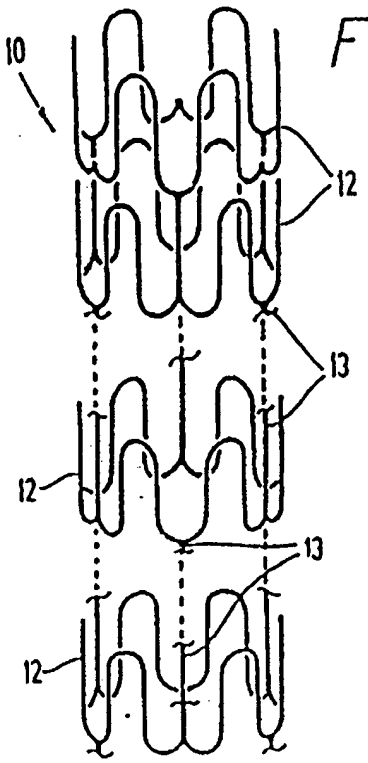



FIG. 6

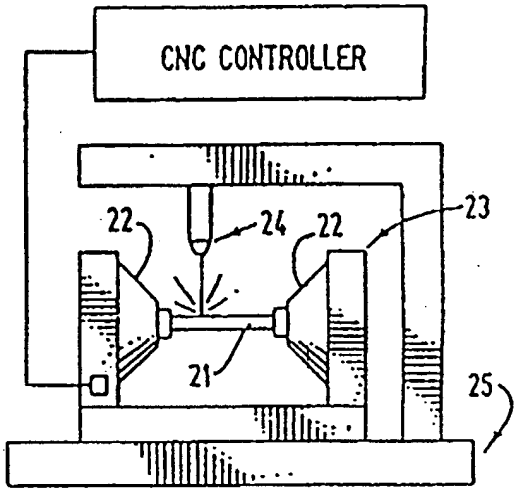



FIG. 5

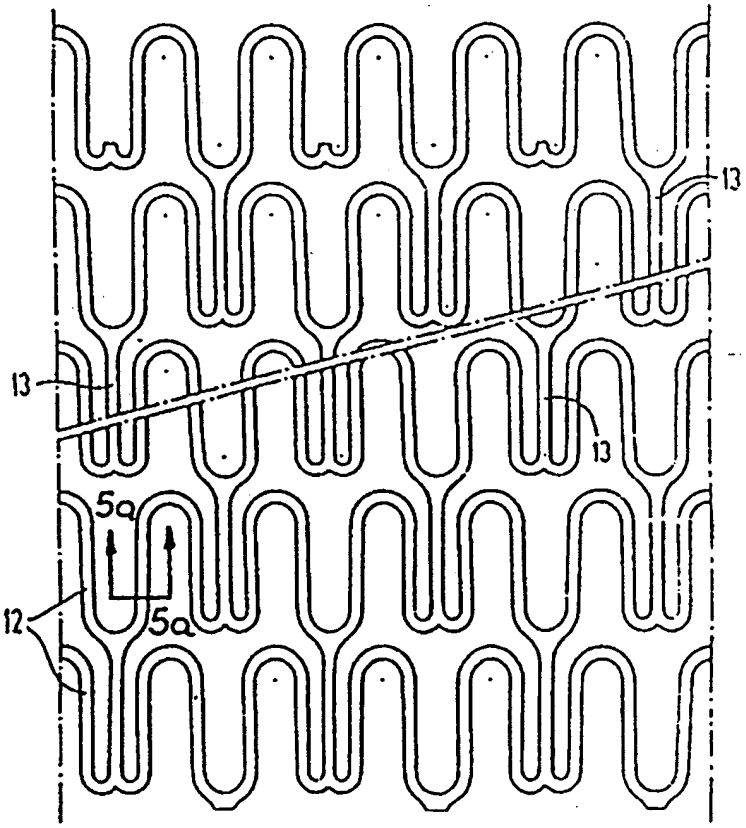
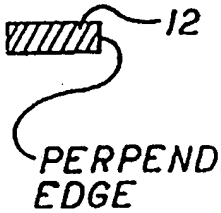



FIG. 5a

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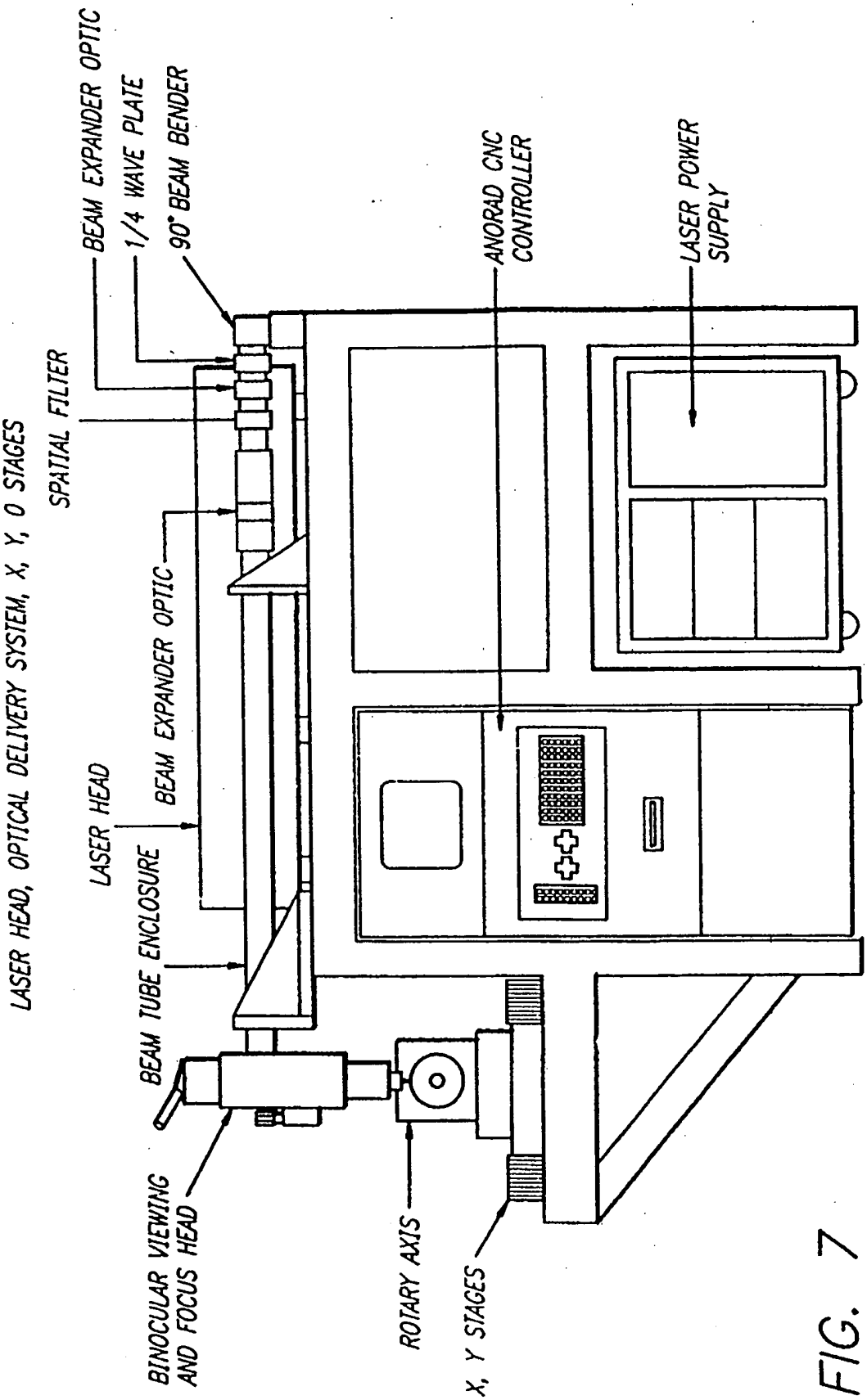


FIG. 7

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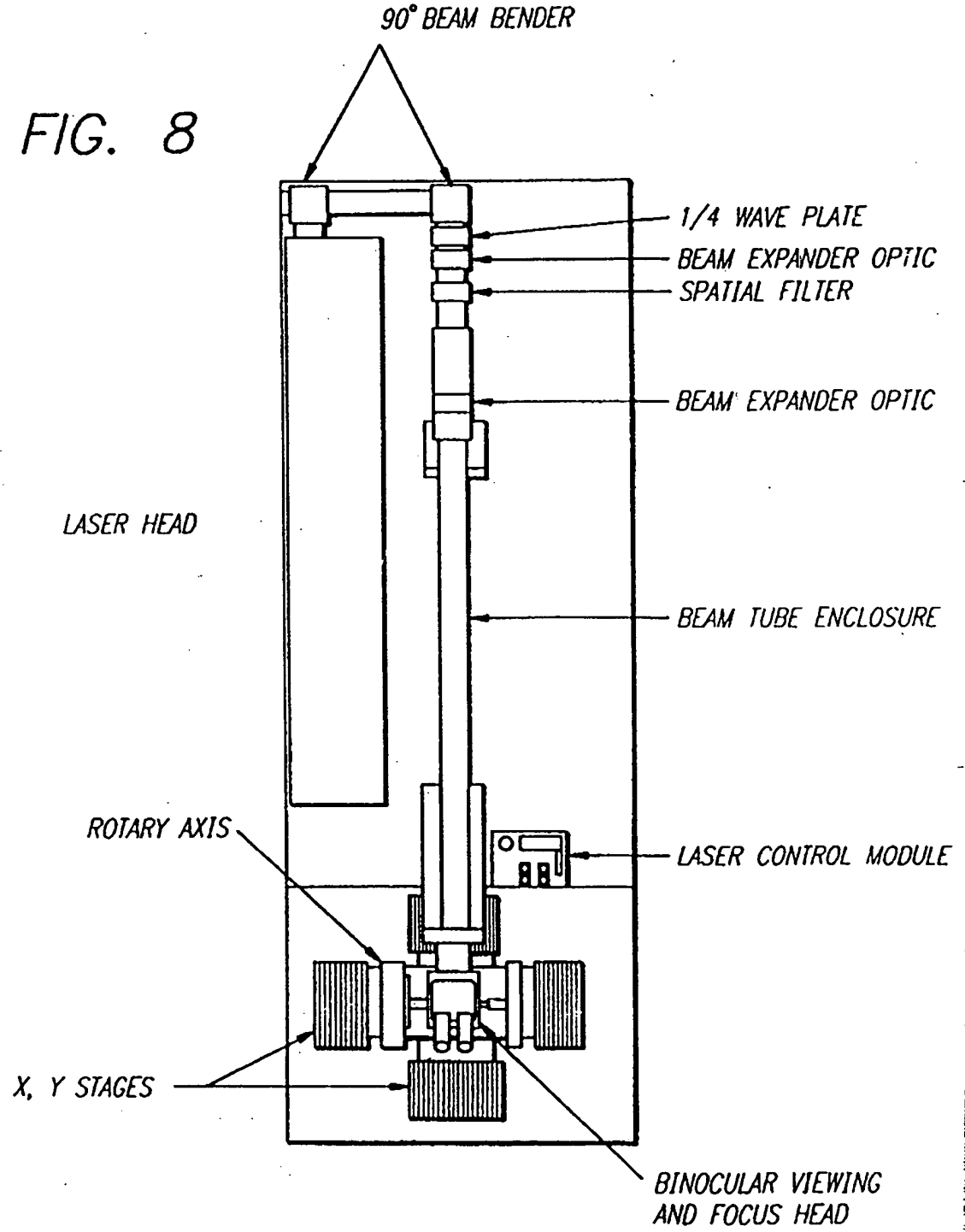
LASER HEAD, OPTICAL DELIVERY SYSTEM, X, Y, O STAGES

FIG. 8

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COAXIAL GAS JET – ROTARY COLLECT AND
TUBE SUPPORT – TUBE BEAM BLOCK

FIG. 9

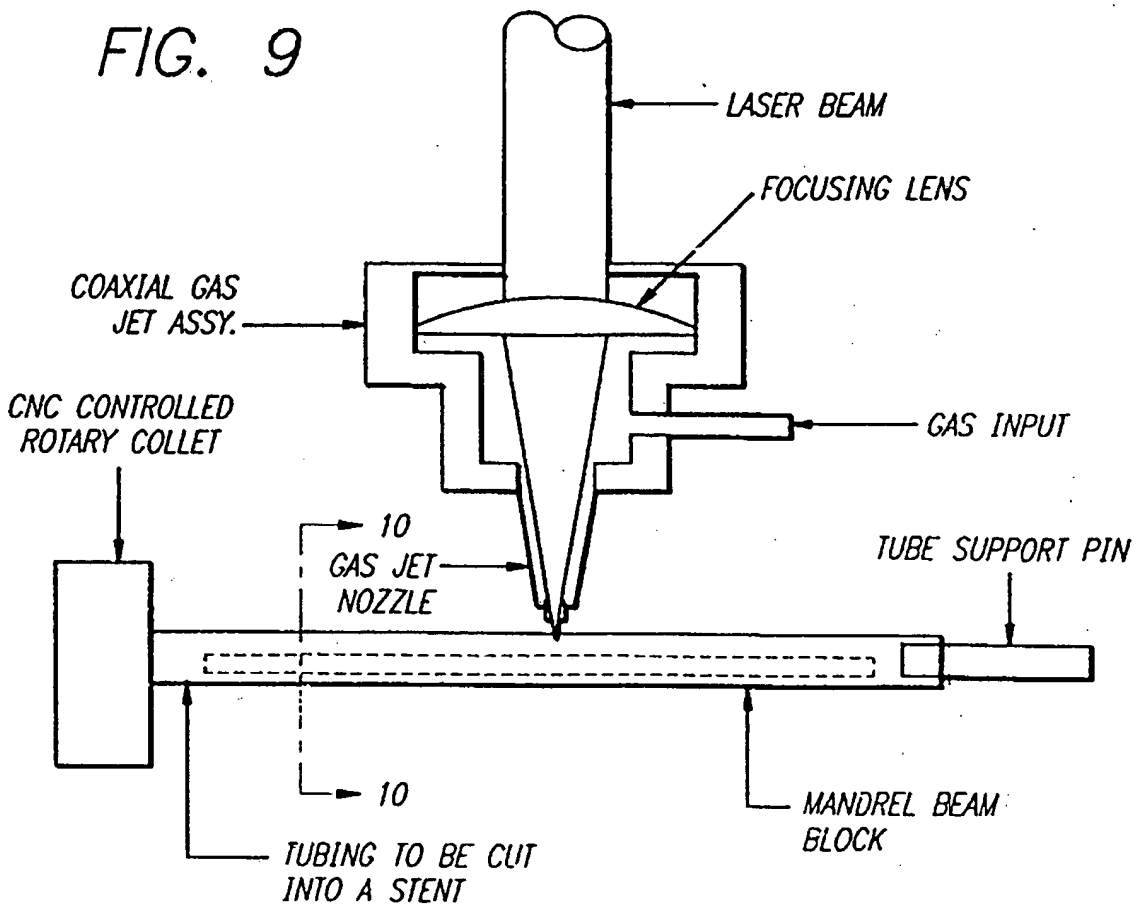


FIG. 10


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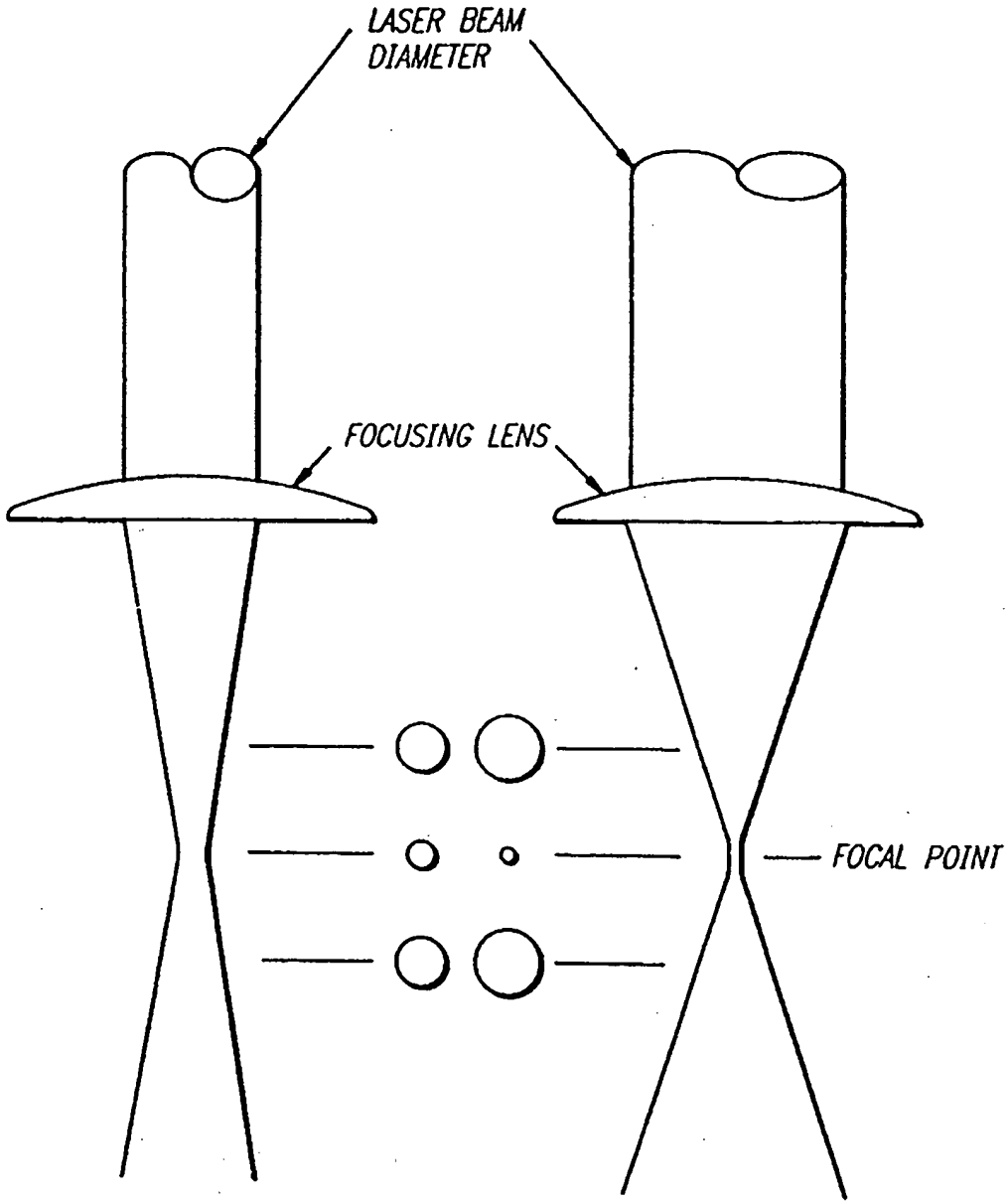
BEAM DIAMETER VS SPOT SIZE AND DEPTH OF FOCUS

FIG. 11

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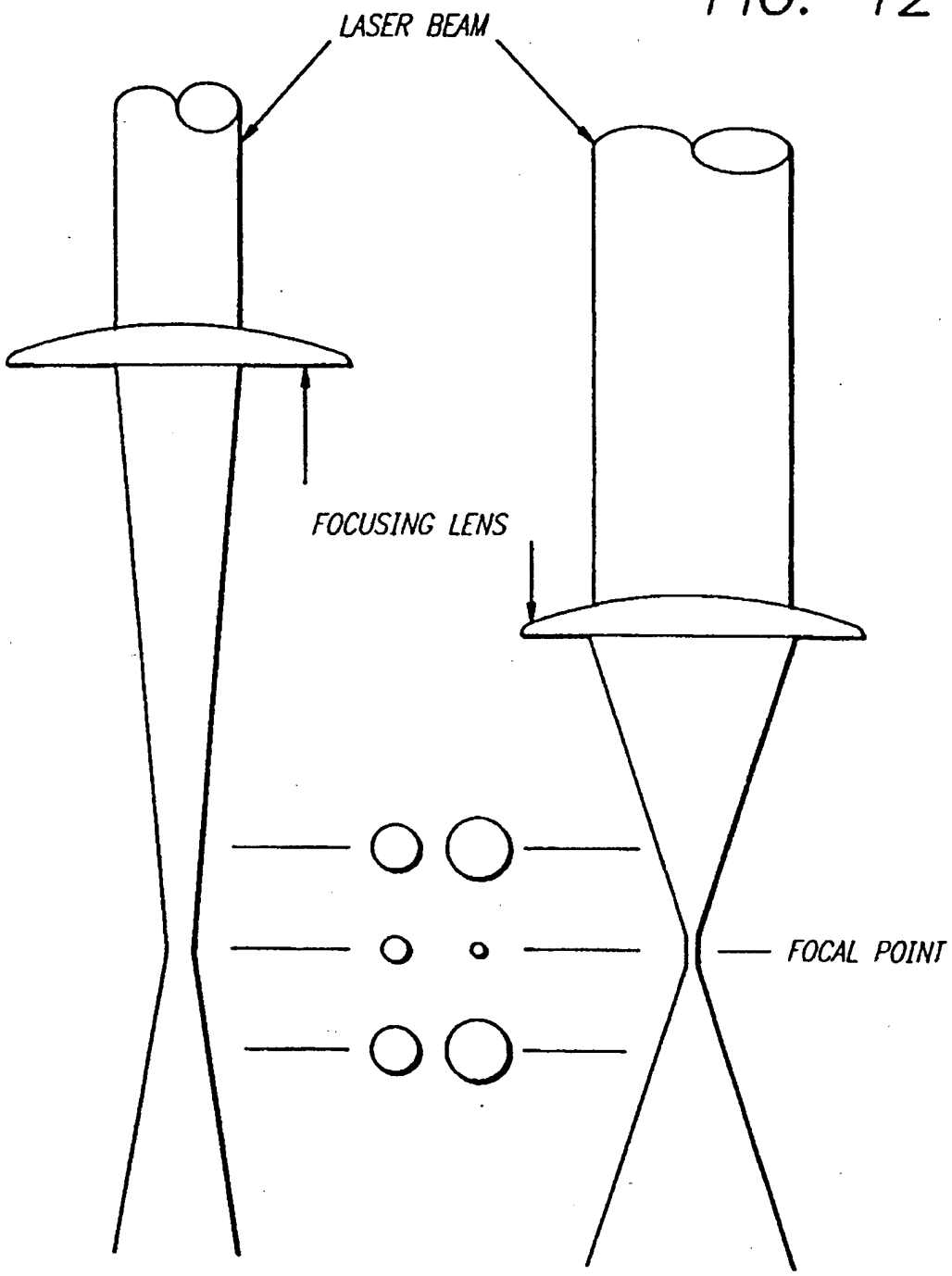
FOCAL LENGTH VS SPOT SIZE AND DEPTH OF FOCUS

FIG. 12

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